## REMARKS

The withdrawal of the rejection for anticipation of claims is appreciated.

The rejection of claims 53 to 60 for obviousness based on Prosl et al is traversed.

The rejection does not state a prima facie case for obviousness because it does not clearly describe now the disclosure in Prosl et al is applied to render obvious the elements of claims 53 and 59. Specifically, there is no statement in the rejection as to what portions of Prosl et al disclose inserting a withdrawal needle and later an withdrawal catheter in a surface peripheral vein.

The claimed invention would not have been obvious in view of the blood treatment device shown in Prosl et al which do not recognize the problem addressed by the inventor or suggest a solution to the problem. Specifically, Prosl et al does not recognize or address the difficulty in withdrawing blood using a needle from a collapsing surface peripheral vein or suggest that a extended catheter may be inserted in the surface peripheral vein that extends through the vein to a larger vein in the patient.

The invention is directed to a method to withdraw blood from a peripheral catheter having an extended length to reach a large or great vein or the vena cava and to a method in which an attempt to withdraw blood is first made by a withdrawal needle in a peripheral vein and thereafter blood is withdrawn by inserting an extended catheter into a peripheral vein to access a reservoir of blood in the large or great vein or vena cava. The claimed invention addresses a problem that arises in ultrafiltration when blood withdrawal through a peripheral vein is insufficient to provide the blood flow, e.g., less

than 40 ml/min, for the intended ultrafiltration treatment. The invention solves this problem by substituting a mid-length catheter for a short catheter needle. The mid-length catheter is introduced into a peripheral vein and extends through the veneous system to a large vein or other reservoir of blood in the patient.

The lack of recognition in the problem addressed by the invention and the lack of a prior art suggestion to solve the problem indicates that the invention would not have been obvious. *Ex parte Hiyamizu*, 10 USPQ2d 1393 (USPTO Bd. Pat. App. & Int. 1988)("it is well settled that where the claimed invention solves a problem, the discovery of the source of the problem and its solution are considered to be part of the "invention as a whole" under 35 U.S.C. 103.").

Prosl et al disclose a "subcutaneous port and catheter assembly" for dialysis. Prosl, Abstract. The subcutaneous port and catheter assembly disclosed in Prosl et al provides a central access directly to a large vein, such as the jugular vein. There is no disclosure in Prosl et al of inserting a catheter in a surface peripheral vein and advancing the catheter to a larger vein. Prosl et al (Fig. 2) discloses a PTFE graft implanted in a patient's arm to provide access for fistula needles. Prosl et al do not suggest that a catheter may be inserted in a PTFE graft and advanced through peripheral veins to a large vein.

The disclosure in Prosl et al (col. 2, lns. 15-33) of an AV Fistula embedded in the arm of a patient and providing direct access to "a major vein subcutaneously in the arm" which is not a surface vein. Prosel et al (col. 4, ln.1) state that the AV Fistula is "seldom used", and require surgical implantation. Prosel et al do not suggest that the AV Fistula

would first receive a withdrawal needle and, if the vein collapses, would receive an extended catheter. Further, an AV Fistula provides direct access to a major vein in the arm and renders unnecessary any need to insert an extended catheter to reach a major vein with a larger blood flow that provided by a surface peripheral vein. The AV Fistula teaches away from the present invention by showing a technique to withdraw blood from a main artery in the arm and thereby avoid the risk of vein collapse that occurs when withdrawing blood through a surface peripheral vein that is narrow and has low blood flow (as compared to a main artery).

Further, Prosl et al proposes an alternative to an AV Fistula. Prosl et al propose a central access subcutaneous port and catheter assembly rather than the surface peripheral vein access for a catheter that is claimed in the rejected claims. Prosl et al disclose a subcutaneous port and catheter assembly to access a central vein. Central venous access lines tend to be much too large for peripheral vein access. It would be counter to such traditional central access blood treatment systems to rely on a narrow peripheral blood catheter to withdraw blood. Prosl et al, at col. 6, lns. 15-19, state a disadvantage of the peripheral access PTFE graft is it provides too little blood. It would have been counter-intuitive to use a narrow peripheral catheter tube to access a central vein. Prosl et al do not teach a method in which blood is first withdrawn from a surface peripheral vein, in which a determination is made that the amount of blood through the surface needle is inadequate and thereafter a catheter is inserted into a peripheral vein of the patient to

"one of a large vein, great vein or vena cava to access a reservoir of blood for continuous blood withdrawal."

Further, Prosl et al do not disclose the following claim elements:

- inserting a withdrawal needle in a surface peripheral vein in an extremity of the patient;
- determining that an insufficient amount of blood is withdrawn through the needle by determining that the withdrawn blood is below a predetermined threshold amount of blood;
- in response to the determination, replacing the needle with a blood withdrawal catheter inserted in the surface peripheral vein, and maneuvering the catheter through the vein to position a tip of the catheter in one of a large vein, great vein or vena cava to access a reservoir of blood for continuous blood withdrawal.

*Secondary Consideration: Invention Recognized by Other As An Advancement In the Art*

Jaski et al is a recognition of the invention in a peer reviewed article. As such, Jaski et al is a secondary consideration of non-obviousness. Jaski et al describes the same ultrafiltration system that is the subject of this application, and is evidence of non-obviousness. The ultrafiltration system described in this application, i.e., made by CHF Solutions, is the subject of the Jaski et al article.[1] [Jaski Article, p. 228.]

[1] Jaski et al was prepared with the technical and financial support of the owner of this application.

Jaski et al is secondary evidence of non-obvious because it shows that "conventional systems" where cumbersome and favorably discusses ultrafiltration using peripheral vein access. Jaski et al is an article published by the Journal of Cardiac Failure and is a peer-reviewed article. The statements in the article regarding the benefits of peripheral access for ultrafiltration and the difficulties with the prior art central access support a finding that the claimed invention was not obvious. The recognition from peers in the art given to the invention in the Jaski et al is a secondary consideration of non-obviousness. *United States v. Adams et al.*, 148 USPQ 479, 484 (U.S. 1966)("Several of the same experts subsequently recognized the significance of the Adams invention.").

Jaski et al describes the use of a mid-length catheter ("25 or 35 cm") with the ultrafiltration system and, thus, is directly relevant to the subject matter claimed in this application. Jaski Article, p. 228. Jaski et al state that: "[t]o our knowledge, this is the first clinical report of rapid removal of extracellular and intravascular fluid volume excess via ultrafiltration without use of a central venous catheter," ("Discussion" heading at page 229); "[r]apid removal of extracellular and intravascular fluid volume excess can be safely achieved via peripherally inserted ultrafiltration without the need for central venous catheter placement" ("Conclusions" heading of the Abstract at page 227); and "[u]se of conventional systems, however, may be cumbersome, requiring physician placement of double-lumen central venous catheter …" ("Background" heading of the Abstract at page 227). Accordingly, Jaski et al teach that central venous catheters are conventional for ultrafiltration, that peripheral vein access with a mid-length catheter

successfully treated patients suffering from circulatory volume overload, and that the use of a mid-length catheter inserted through a peripheral vein was less cumbersome than the prior art technique of central venous catheter access.

All claims are in good condition for allowance. If any small matter remains outstanding, the Examiner is requested to telephone applicants' attorney. Prompt reconsideration and allowance of this application is requested.

The Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, in the fee(s) filed, or asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Account No. 14-1140.

Respectfully submitted,

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